Instructions to User

Dear Users,

Thank you very much for purchasing our product. Please read the manual very carefully before using this device. Failure to follow these instructions can cause measuring abnormality or damage to the oximeter.

The manual is published in English and we have the ultimate right to explain the Manual. No part of this manual may be photocopied, reproduced or translated into another language without the prior written consent. We reserve the right to improve and amend it at any time without prior notice.

Version of the Manual: Ver 1.3

Revised date: March 6, 2012

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Notes

- The contents contained in this manual are subject to change without notice.
- Information furnished by our company is believed to be accurate and reliable. However, no responsibility is assumed by us for its use, or any infringements of patents or other rights of third parties that may result from its use. 3502-1290050

Instructions for Safe Operations

- Check the device to make sure that there is no visible damage that may affect user's safety or measurement performance with regard to sensors and clips. It is recommended that the device should be inspected minimally once a week. When there is obvious damage, stop using the device.
- Necessary maintenance must be performed only by qualified service technicians. Users are not permitted to maintain it by themselves.
- The oximeter cannot be used together with devices not specified in User Manual.

Cautions

- Explosive hazard—**DO NOT** use the oximeter in environment with inflammable gas such as some ignitable anesthetic agents.
- **DO NOT** use the oximeter while the testee is under MRI or CT scanning.

Warnings

- An uncomfortable or painful feeling may appear if using the oximeter continuously on the same place for a long time, especially for poor microcirculation patients. It is recommended that the oximeter

should not be applied to the same location for longer than 2 hours. If any abnormal condition is found, please change the position of oximeter.

- DO NOT clip this device on edema or tender tissue.
- The light (the infrared light is invisible) emitted from the device is harmful to the eyes, so service technician or testee should not stare at the light.
- The local law must be followed when disposing of the device.

Attentions

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- The device should be kept out of the reach of children.
- If the oximeter gets wet, please stop using it and do not resume operation until it is dry. When it is carried from a cold environment to a warm and humid environment, please do not use it immediately.
- **DO NOT** operate the button on the front panel with sharp materials.
- **DO NOT** use high temperature or high pressure steam disinfection on the oximeter. Refer to

Chapter 9 for instructions of cleaning and disinfection.

Declaration of Conformity

The manufacturer hereby declares that this device complies with the following standards:

IEC 60601-1
ISO 9919
and follows the provisions of the council directive MDD93/42/EEC.

Caution: U.S. federal law restricts this device to sale or use by or on the order of a physician.

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1 Overview

1.1 Appearance

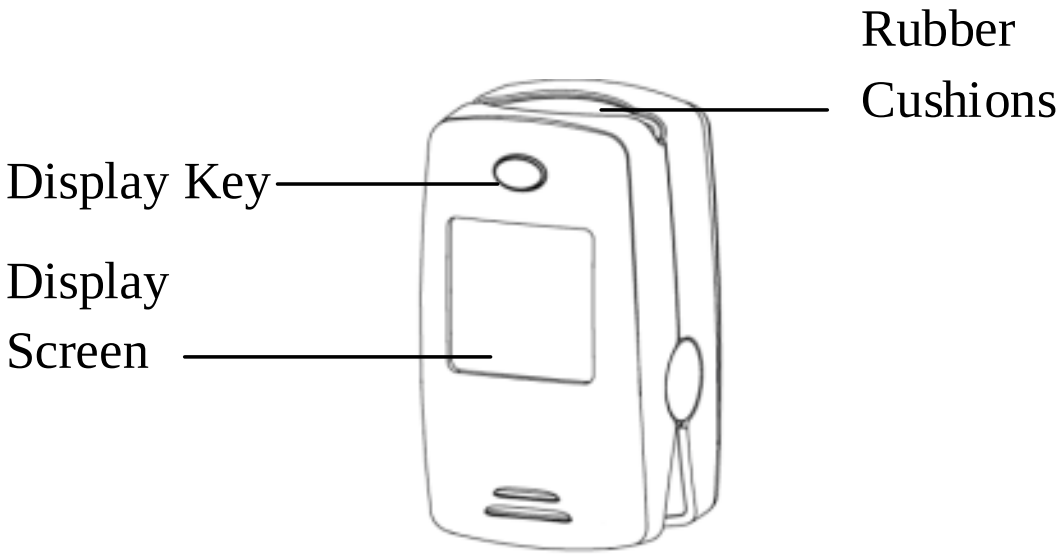


Figure 1 Front View

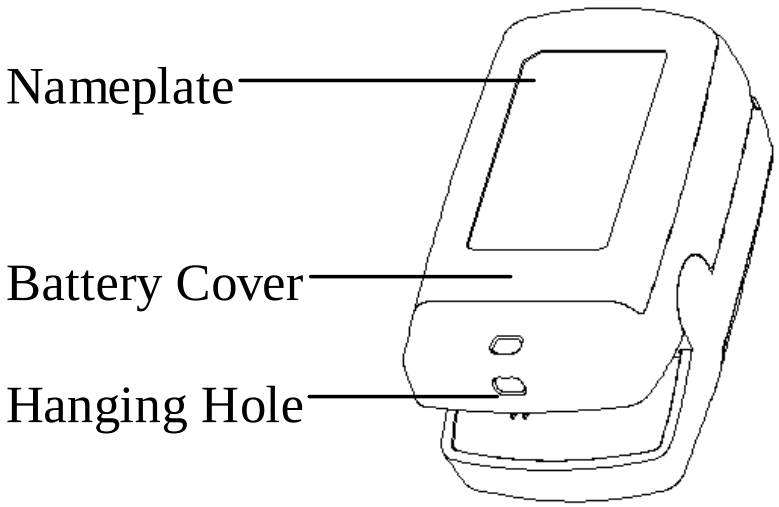


Figure 2 Rear View

1.2 Name

Name: Fingertip Oximeter

1.3 Intended Use

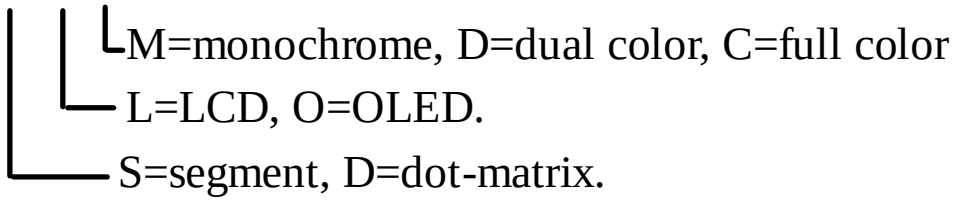
This Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO_2) through patient's finger. It is applicable for spot-checking SpO_2 and pulse rate of adult and pediatric patients in homes and clinics.

1.4 Feature List

Explanation of abbreviations:

Mark: "×" this function is available, "-" without this function.

Display type: X-Y-Z



Note: The finger clip of Style D2 is suitable for small fingers, especially for pediatric patients.

Model / Function	Style A	Style B	Style B1	Style B2	Style B3	Style B5
Display type	S-L-M	S-L-M	D-L-C	D-O-M	D-O-D	D-L-D
SpO_2	×	×	×	×	×	×
PR	×	×	×	×	×	×
PI	-	×	×	×	×	×
Plethysmogram	-	-	×	×	×	×
Auto on	-	×	×	×	×	×
Auto off	×	×	×	×	×	×
Alarm	-	×	×	×	×	×
Low voltage indication	×	×	×	×	×	×
Multi-directional display	-	-	×	×	×	×

Model / Function	Style C	Style C1	Style C2	Style D2	Style E
Display type	D-O-C	D-O-C	D-O-C	D-O-C	D-O-C
SpO_2	×	×	×	×	×
PR	×	×	×	×	×
PI	×	×	×	×	-
Plethysmogram	×	×	×	×	×
Auto on	×	×	×	×	×
Auto off	×	×	×	×	×
Alarm	×	×	×	×	×
Alarm setting	-	×	-	-	-
Pulse beep	-	×	-	-	-
Low voltage indication	×	×	×	×	×
Multi-directional display	×	×	×	×	×

2 Battery Installation

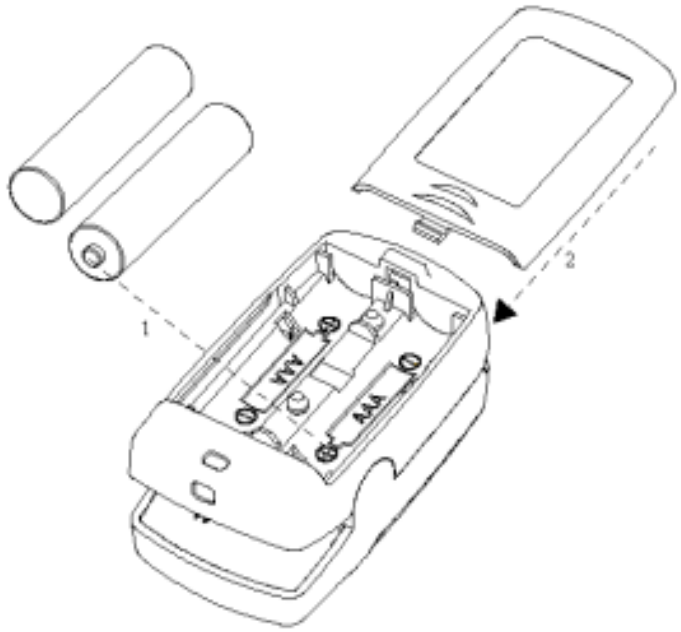


Figure 3 Battery Installation

1. Refer to Figure 3, insert two AAA size batteries into the battery compartment properly.

2. Replace the cover.

⚠ Please make sure that the batteries are correctly installed, or incorrect installation may cause the device not to work.

3 External SpO_2 Probe Connection

Connect the external SpO_2 probe to SpO_2 sensor connector in the following way. Make sure the side with "Arrow" faces upwards.

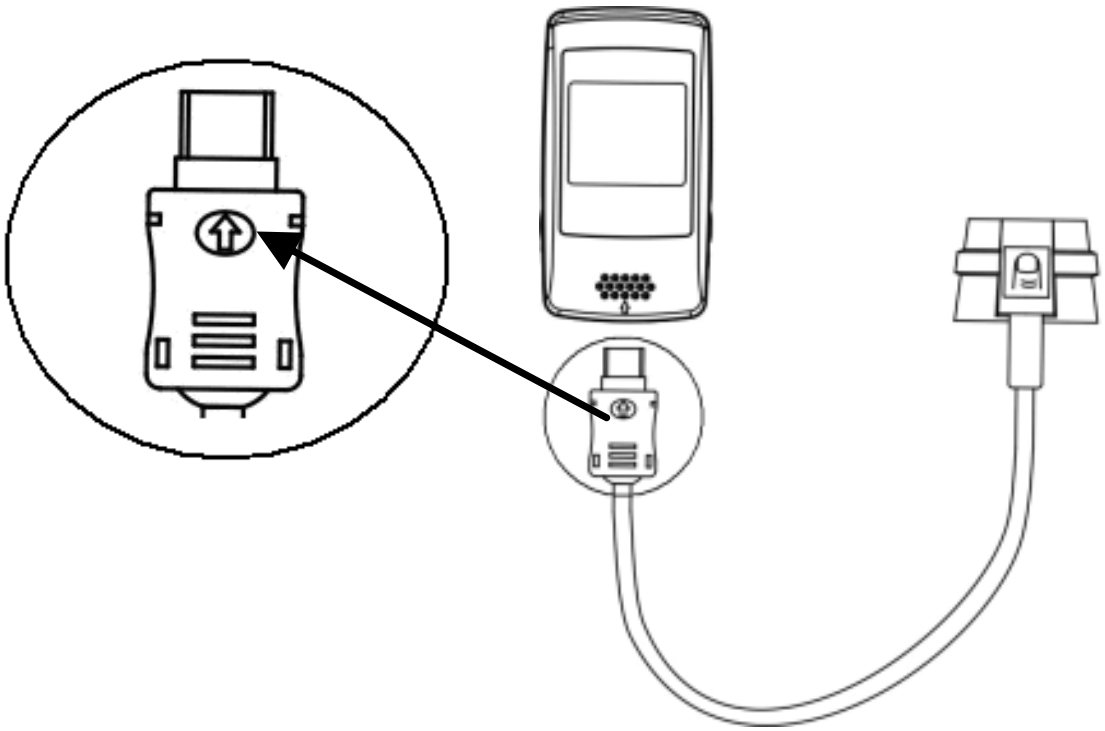


Figure 4 Probe Connection（Special for Style E）

Note: when the external SpO_2 probe is connected well, the built-in finger clip sensor will be disabled. The measurement is detected from the external SpO_2 probe. Meanwhile, the alarm limits for SpO_2 and PR have changed to be: **SpO_2 alarm:** Lower limit: 95%

Pulse Rate alarm: Upper limit: 160bpm

Lower limit: 60bpm

4 Quick Guide to Operation

Step	Operation for Style A, Style B and Style E.	
1	Open the clip and put finger into the rubber cushions of the clip (make sure the finger is in the correct position), and then clip the finger.	
2	For Style B Style E	Wait 2 seconds, the oximeter will power on automatically and start to measure.
	For Style A	Press the display key to start the measurement.
-	For Style B	Short time press Display Key to turn on/off the backlight.
	For Style B	Longtime press Display Key to shift the parameter display between PR and PI.
-	For Style E	Tilt the oximeter to change display direction.
3	Remove your finger, the oximeter will power off automatically.	

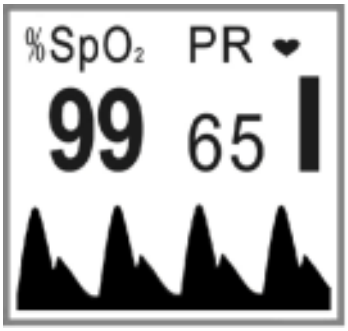
Step	**Operation for Style B1, Style B2, Style B3, Style B5, Style C, Style C2 and Style D2.**
1	Open the clip and put finger into the rubber cushions of the clip (make sure the finger is in the correct position), and then clip the finger.
2	Wait 2 seconds, the oximeter will power on automatically and start to measure.
-	Short time press Display Key to change display direction.
-	Longtime press Display Key to shift the parameter display between PR and PI.
3	Remove your finger, the oximeter will power off automatically.

Step	Operation for Style C1
1	Open the clip and put finger into the rubber cushions of the clip (make sure the finger is in the correct position), and then clip the finger.
2	Wait 2 seconds, the oximeter will power on automatically and start to measure.
-	Tilt the oximeter to change display direction.
-	Short time press Display Key to shift the parameter display between PR and PI.
-	Longtime press Display Key to enter setup menu screen.
-	**On setup menu screen:** Short time press Display Key to choose the setting item; Longtime press Display Key to active the setting item, then short time press it to modify the setting parameter; Next, longtime press Display Key to confirm the modification and exit from this setting item. At last, move the setting item to “Save, exit menu”, and long time pressing Display Key to store the modification and exit from the setup menu.
3	Remove your finger, the oximeter will power off automatically.

5 Display Screen

Measuring screen
(Style A/ B)

PI display screen
(Style B)



Default measuring screen
(Style B1/ B2/B3/ B5/
C/C1/C2/D2 /E)

SpO_2&PI display screen
(Style B1/ B2/B3/
B5/C/C1/C2/D2)

Setup menu screen
(Style C1)

Note: The "Setup menu screen" of PC-60C1 shows the factory default alarm limits setting value which is different from other models.
Low limit setting range: 30-60bpm
High limit setting range: 100-240bpm
Low limit setting range : 85 % ~ 95%

For your oximeter, SpO_2 and PR symbols are imprinted on the front panel and its corresponding value displays on display screen below the symbol. (see figure 5)

Figure 5 **Figure 6**

Short time press display key, display screen (including values,pulse intensity histogram, pulse beat symbol and waveform) will be flipped 180 º. (see figure 6)

Note: The two figures both show that SpO_2 value is 99% and PR value is 86bpm.

6 Instructions for Operation

- The finger should be put in properly and correctly.
- Do not shake the finger. Keep at ease during measurement.
- Do not put wet finger directly into sensor.
- Avoid placing the device on the same limb which is wrapped with a cuff for blood pressure measurement or during venous infusion.
- Do not let anything block the emitting light from device.
- Vigorous exercise and electrosurgical device interference may affect the measuring accuracy.
- The orientation-sensor works on the basis of the gravity. A small movable metal ball is built in the orientation-sensor for detecting the orientation of the oximeter. When you want to change the oximeter's display direction, if you move the oximeter too slowly, the movable metal ball will also move slowly because of not enough acceleration. Consequently the response of orientation detection would be delayed. Please move the oximeter with a bit of force if you want to change the display direction (such as bend/extend your finger quickly), so an acceleration is provided to the orientation-sensor for quick sensing the orientation change.

- Using enamel or other makeup on the nail may affect the accuracy of measurement.
- If the first reading appears with poor waveform (irregular or not smooth), then the reading is unlikely true, the more stable value is expected by waiting for a while, or a restart is needed when necessary.

Note: Due to the working principle of orientation sensor used in Oximeter, there is a small metal ball which is movable within its compartment of the orientation-sensor. Therefore you can hear a slight "clatter" sound when you wave or shake the oximeter. It is normal and not caused by unwanted part.

7 Technical Specifications

A. Power supply requirement:

2 x LR03 (AAA) alkaline batteries

Supply voltage: 3.0VDC

Operating current: ≤40mA

B. SpO_2 Parameter Specifications

Transducer: dual-wavelength LED sensor

Measurement wavelength:

Red light: 663 nm, Infrared light: 890 nm.

Maximal optical output power: less than 1.5mW maximum average

Measuring range: 35~99%

Measuring accuracy:

Not greater than 3% for SpO_2 range from 70% to 100%

*NOTE: Accuracy defined as root-mean-square value of deviation according to ISO 9919.

C. Pulse Rate Parameter Specifications

Measuring range: 30bpm~240bpm

Accuracy: ±2bpm or ±2% (whichever is greater)

D. Perfusion Index(PI) Display

Range: 0%~20%

E. Preset alarm limits

SpO_2 alarm: Lower limit: 90%

Pulse Rate alarm: Upper limit: 120bpm

Lower limit: 50bpm

F. Alarm setting (for StyleC1)

SpO_2 alarm limit

Low limit setting range: 85%~95%

Pulse Rate alarm limit

Low limit setting range: 30~60bpm;

High limit setting range: 100~240bpm;

SpO_2 alarm: default low limit: 85%

Pulse Rate alarm:

default high limit: 120bpm

default low limit: 50bpm

G. Audible &visual alarm function

When measuring, if SpO_2 value or pulse rate value exceeds the preset alarm limit, the device will alarm automatically and the value which exceeds limit on the screen will flash.

H. Environment requirement

Operating Temperature:	5℃ ~40℃
Operating Humidity:	30%~80%
Atmospheric pressure:	70kPa~106kPa

I. The performance under low perfusion condition

The accuracy of SpO_2 and PR measurement still meet the precision described above when the modulation amplitude is as low as 0.6%.

J. Resistance to interference of surrounding light:

The difference between the SpO_2 value measured in the condition of indoor natural light and that of darkroom is less than ±1%.

K. Resistance to 50Hz /60Hz interference:

SpO_2 and PR are precise which have been tested by BIO-TEK pulse oximeter simulator.

L. Dimensions: 66 mm (L) ×36 mm (W) ×33 mm (H)

Net Weight: 60g (including batteries)

M. Classification

The type of protection against electric shock: Internally powered equipment.

The degree of protection against electric shock: Type BF applied parts.

The degree of protection against harmful ingress of liquids: Ordinary equipment without protection against ingress of water.

Electro-Magnetic Compatibility: Group I, Class B

8 Accessories

A. A lanyard
B. Two batteries
C. A pouch
D. An External SpO_2 Probe (optional)
E. A User Manual
F. Quality Certificate

Note: The accessories are subject to change. Detailed items and quantity see the Packing List.

9 Repair and Maintenance

9.1 Maintenance

The life of this device is 5 years. In order to ensure its long service life, please pay attention to the maintenance.

- Please change the batteries when the low-voltage indicator lightens.
- Please clean the surface of the device before using. Wipe the device with alcohol first, and then let it air dry or wipe it dry.
- Please take out the batteries if the oximeter will not be used for a long time.
- The recommended storage environment of the device:

  ambient temperature: -20℃~60℃, relative humidity 10%~95%, atmospheric pressure: 50kPa~107.4kPa.
- The oximeter is calibrated in the factory before sale, there is no need to calibrate it during its life cycle. However, if it is necessary to verify its accuracy routinely, the user can do the verification by means of SpO_2 simulator, or it can be done by the local third party test house.

⚠ **High-pressure sterilization cannot be used on the device.**

⚠ **Do not immerse the device in liquid.**

⚠ **It is recommended that the device should be kept in a dry environment. Humidity may reduce the life of the device, or even damage it.**

9.2 Cleaning and Disinfecting Instruction

- Surface-clean sensor with a soft cloth by wetting with a solution such as 75% isopropyl alcohol, if low-level disinfection is required, use a 1:10 bleach solution.
- Then surface-clean with a cloth saturated with clean water and dry with a clean, soft cloth.

Caution: Do not sterilize by irradiation steam, or ethylene oxide.

Do not use the sensor if it is damaged.

10 Troubleshooting

Trouble	Possible Reason	Solution
Display direction doesn’t change or changes insensitively.	Maybe the oximeter is not used for a long time, the movable metal ball within the orientation-sensor can not move freely.	Please shake the oximeter with a certain force to make the movable metal ball move freely. If the problem still exists, maybe the orientation-sensor is not working properly. Please contact the local service center.

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate display instable	1. The finger is not placed far enough inside. 2. The finger is shaking or the patient is moving.	1. Place the finger correctly inside and try again. 2. Let the patient keep calm.
Can not turn on the device	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The device is malfunctioning.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
No display	1. The device will power off automatically when it gets no signal for 8 seconds. 2. The batteries are almost drained.	1. Normal. 2. Change batteries.

Appendix

Ⅰ Key of Symbols

Symbol	Description
%Spo_2	Pulse oxygen saturation
BPM/PR	Pulse rate (beats per minute)
PI%	Perfusion Index (%)
	Pulse intensity bargraph
	Low battery voltage
SN	Serial number
	Date of manufacture
	With Type BF applied part
	Warning — See User Manual
	Disposal of this device according to WEEE regulations

Ⅱ Common Knowledge

1 Meaning of SpO_2

SpO_2 is the saturation percentage of oxygen in the blood, so called O_2 concentration in the blood; it is defined by the percentage of oxyhemoglobin (HbO_2) in the total hemoglobin of the arterial blood. SpO_2 is an important physiological parameter to reflect the respiration function; it is calculated by the following method:

$$\mathbf{SpO_2 = HbO_2 / (HbO_2 + Hb) \times 100\%}$$

HbO_2 are the oxyhemoglobins (oxygenized hemoglobin), Hb are those hemoglobins which release oxygen.

2 Principle of Measurement

Based on Lamber-Beer law, the light absorbance of a given substance is directly proportional with its density or concentration. When the light with certain wavelength emits on human tissue, the measured intensity of light after absorption, reflecting and attenuation in tissue can reflect the structure character of the tissue by which the light passes. Due to that oxygenated hemoglobin (HbO_2) and deoxygenated hemoglobin (Hb) have different absorption character in the spectrum range from red to infrared light

(600nm~1000nm wavelength), by using these characteristics, SpO_2 can be determined. SpO_2 measured by this oximeter is the functional oxygen saturation -- a percentage of the hemoglobin that can transport oxygen. In contrast, hemoximeters report fractional oxygen saturation – a percentage of all measured hemoglobin, including dysfunctional hemoglobin, such as carboxyhemoglobin or metahemoglobin.

Clinical application of pulse oximeters: SpO_2 is an important physiological parameter to reflect the respiration and ventilation function, so SpO_2 monitoring used in treatment has become more popular. (For example, such as monitoring patients with serious respiratory disease, patients under anesthesia during operation and premature and neonatal infants) The status of SpO_2 can be determined in timely manner by measurement and will allow finding the hypoxemia patient earlier, thereby preventing or reducing accidental death caused by hypoxia effectively.

3 Factors affecting SpO_2 measuring accuracy (interference reason)

- ✧ Intravascular dyes such as indocyanine green or methylene blue
- ✧ Exposure to excessive illumination, such as surgical

lamps, bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight.

- ✧ Vascular dyes or external used color-up product such as nail enamel or color skin care
- ✧ Excessive patient movement
- ✧ Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- ✧ Exposure to the chamber with High pressure oxygen
- ✧ There is an arterial occlusion proximal to the sensor
- ✧ Blood vessel contraction caused by peripheral vessel hyperkinesias or body temperature decreasing

4 Factors causing low SpO_2 Measuring value (pathology reason)

- ✧ Hypoxemia disease, functional lack of HbO_2
- ✧ Pigmentation or abnormal oxyhemoglobin level
- ✧ Abnormal oxyhemoglobin variation
- ✧ Methemoglobin disease
- ✧ Sulfhemoglobinemia or arterial occlusion exists near sensor
- ✧ Obvious venous pulsations
- ✧ Peripheral arterial pulsation becomes weak
- ✧ Peripheral blood supply is not enough

Quality Certificate

Name: _____

Model: _____

Date: _____

QA: _____

This Product has been inspected in accordance with the standards specified in User's Manual